NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of insertion of an annular disc implant at lumbar discectomy

The tough covering of a spinal disc (annulus) can sometimes break, allowing the soft centre to bulge through. This is called herniation, also known as 'slipped disc'. This may cause pain in the back and leg, and numbness and weakness in the leg ('sciatica'). Inserting an annular disc implant involves removing the bulging part of the disc (lumbar discectomy) and inserting an implant to close the hole that is left in the disc. The aim is to reduce the risk of further herniation.

Introduction

The National Institute for Health and Care Excellence (NICE) has prepared this interventional procedure (IP) overview to help members of the Interventional Procedures Advisory Committee (IPAC) make recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This IP overview was prepared in March 2014.

Procedure name

- Insertion of an annular disc implant at lumbar discectomy

Specialist societies

- British Association of Spinal Surgeons.

Description

Indications and current treatment

Lumbar disc herniation occurs when the nucleus pulposus of an intervertebral disc protrudes through a tear in the surrounding annulus fibrosus. Symptoms include pain in the back or leg, and numbness or weakness in the leg. Serious neurological sequelae may sometimes occur.

Conservative treatments include analgesics, non-steroidal anti-inflammatory medication and physical therapy. Epidural corticosteroid injections can also be used to reduce nerve pain in the short term. Lumbar discectomy is considered if there is evidence of severe nerve compression or persistent symptoms that are unresponsive to conservative treatment. Surgical techniques include open discectomy or minimally invasive alternatives using percutaneous approaches.

Lumbar discectomy usually leaves a hole in the annulus fibrosus through which the nucleus herniated, which may lead to reherniation and progressive loss in disc height.

What the procedure involves

Insertion of an annular disc implant at lumbar discectomy aims to reduce the incidence of recurrent herniation and the degree of intervertebral disc collapse.

With the patient under general anaesthesia, the herniated disc material is removed and the annular disc device is implanted. The device typically contains a metallic bone-anchoring component and a woven polymer mesh. The bone-anchoring component is inserted using a mallet and tamp into one of the vertebral bodies adjacent to the discectomy site, and the woven mesh component is inserted into the annular disc defect, so covering the residual nucleus pulposus. Fluoroscopy may be used to guide the procedure.

Clinical assessment

The Oswestry Disability Index (ODI) measures degrees of disability in a person with low back pain. The index is scored from 0 to 100, 0 indicating no disability and 100 maximum disability.

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to insertion of an annular disc implant at lumbar discectomy. Searches were conducted of the following databases, covering the period from their commencement to 16 July 2014:

MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches (see appendix C for details of search strategy). Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

The following selection criteria (table 1) were applied to the abstracts identified by the literature search. Where selection criteria could not be determined from the abstracts the full paper was retrieved.

Table 1 Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies were included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, or a laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising study methodology, unless they reported specific adverse events that were not available in the published literature.
Patient	Patients with symptomatic herniated lumbar intervertebral disc.
Intervention/test	Insertion of an annular disc implant at lumbar discectomy.
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

List of studies included in the IP overview

This IP overview is based on approximately 332 patients from 3 non-randomised comparative studies[1–3] and 2 case series[4,5].

Table 2 Summary of key efficacy and safety findings on insertion of an annular disc implant at lumbar discectomy

Study 1 Trummer M (2013)

Details

Study type	**Prospective non-randomised comparative study**
Country	Europe
Recruitment period	Not reported
Study population and number	**n=157 (63 discectomy plus annular disc implant versus 94 discectomy only)**
Age and sex	Mean 40.5 years; male:female=1.1:1 for the implant group and 1.7:1 for the control group.
Patient selection criteria	**Inclusion criteria:** patients with a confirmed primary lumbar disc herniation with at least 6 weeks of failed conservative treatment before surgery. Patients with leg pain measured by VAS≥40/100. For implant group: disability graded by ODI≥40/100 and annulus defect greater than 6 mm in height or 10 mm in width because of limitations in available implant sizes. Patients aged between 18 and 75 years. Patients were included in the discectomy-only group before the implant was available clinically. **Exclusion criteria:** patients with spondylolisthesis Grade II or higher, prior surgery at the index level, bone density t-scores <−2.0 for subjects requiring DEXA, patients who had clinically compromised vertebral bodies in the lumbosacral region due to any traumatic, neoplastic, metabolic, or infectious pathology, and scoliosis >10º.
Technique	In the implant group, patients who met the defect size criteria had the annular disc implant (Barricaid ARD, Intrinsic Therapeutics, Woburn, MA USA) inserted after the evacuation of the disc tissue during microdiscectomy. In the control group, patients were treated by standard microdiscectomy. An independent radiologist who was not blind to treatment allocation used axial CT and a 4-point scale to grade facet joint osteoarthritis.
Follow-up	**12 months**
Conflict of interest/source of funding	Funding was provided in part by Intrinsic Therapeutics, Inc.

Analysis

Follow-up issues:

- At the start, a total of 212 patients (75 implant versus 137 discectomy-only patients) were enrolled in the study design. Total lost to follow-up: 55 patients (26%).

Study design issues:

- Only 1 radiologist interpreted the CT scans and he was not blinded to the treatment and control groups at follow-up.
- One patient from the implant group was implanted in 2 levels, yielding 64 implants for 63 patients.
- Multicentre study.

Study population issues:

- Age was not significantly different between the 2 groups.
- Suspected overlap between the implant population studied (63 patients) and the patient population from the Bouma paper[4] but reporting different outcomes.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **157 (63 versus 94)**

Facet grade (authors only present percentages, absolute numbers not given)

	Preoperatively		12 months post-discectomy	
Grade*	**Implant (128 facets)**	**Control (188 facets)**	**Implant (128 facets)**	**Control (188 facets)**
0	49%	35%	38%	22%
I	45%	59%	55%	62%
II	3%	6%	5%	15%
III	2%	0%	2%	1%

* Facet grade scale: 0–3 from normal to severe

- When grouping grades 0 and 1 versus grades 2 and 3, there was no difference between both groups (p=1.000) preoperatively.
- When grouping grades 0 and 1 versus grades 2 and 3, the control group had a higher grade of facet degeneration than the implant group (p=0.015) 12 months post-discectomy.

Facet degeneration at 12 months

	Implant	Control	p
% of patient exhibiting facet degeneration	23% (15/64)	43% (40/94)	0.017
% of patient exhibiting facet degeneration when both groups were restricted to the same (more restrictive) ODI and defect size requirements	24% (15/62)	51% (18/35)	0.008

Progression of the facet degeneration (no p values given)

Progression	Implant	Control
To mild (Grade I)	19% (12/64)	26.6% (25/94)
To moderate (Grade II)	5% (3/64)	15% (14/94)
To severe degenerative disease (Grade III)	0	1% (1/94)

No patient exhibited a change of more than 1 grade.

Progression when both groups were restricted to the same (more restrictive) ODI and defect size requirements	Implant	Control
To mild (Grade I)	19% (12/62)	31% (11/35)
To moderate (Grade II)	5% (3/62)	20% (7/35)
To severe degenerative disease (Grade III)	0	0

Range of motion

Preoperatively, both groups exhibited similar angular ranges of motion (p=0.6162).

At 12 months, the implant group exhibited a greater range of motion (p=0.0092).

Facet degeneration risk

A lower probability for facet degeneration was significantly correlated with smaller annular defects (p=0.041) and discs implanted with the device (p=0.014).

Other clinical outcomes

There were no significant differences in any of the clinical outcome scores (ODI, VAS-Back, VAS-Ipsilateral-Leg) between patients who exhibited facet degeneration and those who had not when both groups were combined or taken separately.

Safety

No cases of implant migration, subsidence, disassembly or fracture were reported or observed.

Abbreviations used: DEXA, dual-energy X-ray absorptiometry; MRI, magnetic resonance imaging; ODI, Oswestry Disability Index; VAS, Visual Analogue Scale.

Study 2 Vukas D (2013)

Details

Study type	**Prospective non-randomised comparative study**
Country	Croatia
Recruitment period	2003–09
Study population and number	**n=102 (30 discectomy plus annular disc implant versus 72 discectomy only)**
Age and sex	Mean 39.4 years; 64% (65/102) male
Patient selection criteria	**Inclusion criteria:** patients suffering from neurologic deficit (radiculopathy) caused by disc herniation (confirmed by MRI) for at least 6 weeks and no improvement with conservative treatment. Implant group: patients with leg pain measured by VAS≥40/100, disability graded by ODI≥40/100, and annulus defect greater than 6 mm in height or 10 mm in width because of limitations in available implant sizes. **Exclusion criteria:** previous spine surgery, foraminal or extraforaminal disc herniation, other spinal pathology, and/or systemic or metabolic diseases.
Technique	All patients were administered antibiotic prophylaxis (cefazolin) before the procedure. In the control group, patients were treated by standard microdiscectomy. In the implant group, patients who met the defect size criteria had the annular disc implant (Barricaid ARD, Intrinsic Therapeutics, Woburn, MA USA) inserted after the evacuation of the disc tissue during the microdiscectomy.
Follow-up	**24 months**
Conflict of interest/source of funding	Not reported

Analysis

Follow-up issues:

- Patients lost to follow-up not reported.

Study design issues:

- 2 groups of patients recruited non-concurrently: control group received discectomy between 2003 and 2007 and implant group received it in 2008 and 2009.

Study population issues:

- Suspected overlap between the implant group (30 patients) and the treatment cohort from the Parker paper reporting the same efficacy and safety outcomes but compared with a different population[3].
- Other suspected overlap with the cohort A of the Bouma paper[4].
- Mean preoperative ODI different for control and implant groups: 49.4 versus 62.7 (p=0.0004).

Key efficacy and safety findings

Efficacy

Number of patients analysed: **102 (30 versus 72)**

Mean ODI*

Time point	Implant	Control	p
Preoperative	62.7	49.4	0.0004
Week 6	31.4	30.7	0.7505
Month 3	22.6	25.6	0.4239
Month 6	17.7	21.6	0.3639
Month 12	15.6	19.8	0.2743
Month 24	11.6	19.8	0.0763

* Higher scores representing more severe disability

Mean VAS** measuring back pain

Time point	Implant	Control	p
Preoperative	66.3	43.1	0.0000
Week 6	18.1	22.5	0.3770
Month 3	12.1	22.8	0.0560
Month 6	14.1	23.4	0.2100
Month 12	13.2	21.0	0.1360
Month 24	10.5	19.1	0.2725

** Higher scores representing more severe pain

Mean VAS** measuring pain in the affected leg

Time point	Implant	Control	p
Preoperative	79.8	58.8	0.0001
Week 6	12.7	17.4	0.2568
Month 3	9.2	19.0	0.0558
Month 6	12.3	17.1	0.6961
Month 12	4.7	13.6	0.0160
Month 24	8.9	21.2	0.0046

** Higher scores representing more severe pain

Reherniation rate

	Implant	Control
Within 3 months post-surgery	0	2.8% (2/72)
Between 4 months and 2 years post-surgery	0	4.2% (3/72)

Safety

- No intraoperative complications due to the modification of the standard procedure.
- Durotomy: 3.3% (1/30) for the implant group versus 1.4% (1/72) for the control group.

Abbreviations used: DEXA, dual-energy X-ray absorptiometry; MRI, magnetic resonance imaging; ODI, Oswestry Disability Index; VAS, Visual Analogue Scale.

Study 3 Parker SL (2014)

Details

Study type	**Prospective controlled non-randomised comparative cohort study**
Country	Not reported.
Recruitment period	Treatment cohort: May 2008 – May 2009. Control cohort: January 2003 – May 2006.
Study population and number	**n=76 (30 in the treatment cohort and 46 in the control cohort)**
Age and sex	Mean age in the treatment cohort: 38 years; in the control cohort: 41 years. Sex ratio not reported.
Patient selection criteria	**Inclusion criteria:** Failed conservative treatment before surgery ≥ 6 weeks or neurological deficit. Disc herniation localising to radicular symptoms, confirmed by a pre-operative MRI. Patients with leg pain measured by VAS≥40/100. Disability graded by ODI≥40/100. Patients aged between 18 and 70 years. **Exclusion criteria:** History of a previous back operation. Foraminal or extraforaminal disc herniation. Extraspinal cause of sciatica. Active medical or workman's compensation lawsuit. Any pre-existing spinal pathology. Unwilling or unable to participate with follow-up procedures. Notable non-intervertebral disc abnormalities.
Technique	Patients were treated by 3 surgeons over 2 cohorts. All patients received prophylactic antibiotics at incision. Patients who could not have the discectomy performed through the interlaminar space alone had a small unilateral laminotomy performed. The patients from the treatment cohort received implantation of the annular closure device (Barricaid, Intrinsic Therapeutics, Woburn, MA USA) at the completion of the discectomy. Patients from the control cohort underwent discectomy without any form of annular closure.
Follow-up	**24 months**
Conflict of interest/source of funding	Funding was provided by Intrinsic Therapeutics, Inc. Dr Carragee owns stock options with the company and Matthew J. McGirt is a paid consultant for the company.

Analysis

Follow-up issues:

- All patients followed up for 24 months for recurrent disc herniation.
- 100% (30/30) of patients in the implant group and 72% (33/46) of patients in the control group followed up at 12 months and 96% (29/30) of patients in the implant group versus 54% (25/46) of patients in the control group followed up at 24 months for disc height measurement.
- 100% (30/30) of patients in the implant group versus 83% (38/46) in the control group and 96% (29/30) of patients in the implant group versus 50% (23/46) of patients in the control group completed their patient-reported outcomes assessment 12 months after surgery and 24 months after surgery respectively.

Study design issues:

- Study conducted at 2 university medical institutions for both control and treatment groups.

Study population issues:

- Suspected overlap between the treatment cohort (30 patients) and the implant population from the Vukas paper reporting the same efficacy and safety outcomes but compared with a different population[2].
- Other suspected overlap with the cohort A of the Bouma paper[4].

Other issues: none.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **76 (30 versus 46)**

Recurrent disc herniation 24 months after surgery

- 0% versus 6.5% (3/46) of patients in the control group.
- Difference not significant (p=0.27).

Loss of disc height

Time point	Implant (mm)	Control (mm)	p
Preoperative	8.6	8.3	
Month 3	7.9	7.27	0.08
Month 6	7.81	7.18	0.09
Month 12	7.63	6.9	0.054

Patient-reported outcomes

- Significant improvements (p<0.01) in VAS-LP, VAS-BP, and ODI observed at 6 weeks, 3, 6, 12, and 24 months in both cohorts.

Patient-reported outcomes at 12 months (higher score=worse outcome)

Scale	Implant	Control	p
VAS-LP	5	16	<0.01
VAS-BP	13	22	<0.05
ODI	16	22	<0.05

Patient-reported outcomes at 24 months (higher score=worse outcome)

Scale	Implant	Control	p
VAS-LP	9	18	<0.05
VAS-BP	10	21	<0.05
ODI	11	21	<0.05

Patient-reported outcomes: mean 12-month improvement from baseline

Scale	Implant	Control	p
VAS-LP	75	53	<0.001
VAS-BP	53	31	<0.001
ODI	47	35	<0.005

Safety

- No device-related morbidity during implantation, inability to place the device, or post-operative device migration reported.

Durotomy

- Implant cohort: 3.3% (1/30) of patients. Occurred during disc fragment removal and authors stated this was not related to placement of the annular closure device.
- Control cohort: 2.2% (1/46) of patients.

Peri-operative morbidity

- Implant cohort: 3.3% (1/30) of patients underwent disc debridement and wound incision and drainage for suspected discitis 56 days after primary surgery. The annular closure device was left in situ and discitis resolved with intravenous antibiotic therapy
- Control cohort: none.

Abbreviations used: DEXA, dual-energy X-ray absorptiometry; MRI, magnetic resonance imaging; ODI, Oswestry Disability Index; VAS, Visual Analogue Scale.

Study 4 Bouma GJ (2013)

Details

Study type	**Prospective case series within 2 different patient cohorts**
Country	Europe (6 different sites)
Recruitment period	Cohort A: from 2008 Cohort B: from 2009
Study population and number	**n=75 (30 in cohort A and 45 in cohort B)**
Age and sex	Mean 40.7 years; 53% (40/75) male
Patient selection criteria	**Inclusion criteria:** Patients with a confirmed primary lumbar disc herniation with at least 6 weeks of failed conservative treatment before surgery. Patients with leg pain measured by VAS≥40/100, disability graded by ODI≥40/100, and annulus defect greater than 6 mm in height or 10 mm in width because of limitations in available implant sizes. Patients aged between 18 and 75 years. **Exclusion criteria:** patients with spondylolisthesis Grade II or higher, prior surgery at the index level, bone density *t*-scores <−2.0 for subjects requiring DEXA, and scoliosis >10º.
Technique	Patients were treated by 10 surgeons over the 2 cohorts. Patients who met the defect size criteria had the annular disc implant (Barricaid ARD, Intrinsic Therapeutics, Woburn, MA USA) inserted after the evacuation of the disc tissue during the microdiscectomy.
Follow-up	**24 months**
Conflict of interest/source of funding	The authors report none. Intrinsic Therapeutics provided support for the clinical research and data analysis.

Analysis

Follow-up issues:

- Cohort A: all 30 patients completed 12-month follow-up, 97% (29/30) completed 24-month follow-up.
- Cohort B**:** 2 patients were excluded from the analysis because of intraoperative procedural errors that resulted in no device being implanted. 95% (41/43) of the patients completed 12-month follow-up, and 26% (11/43) completed 24-month follow-up at the time of publication. Revision surgery and device removal was performed on 1 patient before the 12-month time-point. Therefore, data from only 40 patients in Cohort B were analysed at 12 months.

Study design issues:

- Multicentre study.
- Author states: 'Possible differences in patient demographics or surgical technique between the two cohorts that may have influenced the outcomes.'

Study population issues:

- Suspected overlap between the patient population (63 out of 75 patients) and the studied implant population from the Trummer paper but reporting different outcomes[1].
- Other suspected overlap between cohort A (30 patients) and the implant populations of the Vukas and Parker papers[2, 3].

Other issues:

- In 1 patient in Cohort A, the device was implanted at 2 levels.
- One patient from Cohort B was a protocol deviation with a preoperative VAS leg score <40. This patient was included in the analysis of reherniations.
- No detailed results for the clinical outcomes for pain and function.

Key efficacy and safety findings

Efficacy	Safety
Number of patients analysed: **73** ***Reherniation rate*** • Overall symptomatic reherniation rate: 1.4% (1/73) • Asymptomatic reherniation rate (after MRI review): 1.5% (1/66) at 12 months and 5.1% (2/39) at 24 months.	No safety findings were reported in the paper.
Abbreviations used: DEXA, dual-energy X-ray absorptiometry; MRI, magnetic resonance imaging; ODI, Oswestry Disability Index; VAS, Visual Analogue Scale.	

Study 5 Lequin MB (2012)

Details

Study type	**Prospective case series**
Country	Not reported
Recruitment period	April 2009 to July 2010
Study population and number	**n=45**
Age and sex	Mean 42.3 years; 53% (24/21) male
Patient selection criteria	**Inclusion criteria:** Patients aged between 18 and 75 years. Posterior or posterolateral disc herniations at 1 or 2 levels between L1 and S1 with radiographic confirmation of neural compression. Failed conservative treatment before surgery≥ 6weeks. Minimum posterior disc height of 3 mm at the index level(s). ODI≥40/100 VAS leg pain≥40/100 **Exclusion criteria:** Spondylolisthesis ≥Grade II. Requires uni- or bilateral facetectomy to treat leg/back pain. Back or non-radicular leg pain of unknown aetiology. Prior disc surgery at the index lumbar vertebral level, including fusion, motion preservation, facetectomy or intradiscal electrothermal therapy. Requires a spine DEXA with a T-score <−2 at the index level. Clinically compromised vertebral bodies at the index level(s) due to any traumatic, neoplastic, metabolic, or infectious pathology. BMI>40.
Technique	Patients were treated by 8 neurosurgeons in 4 different sites. Patients who met the defect size criteria had the annular disc implant (Barricaid ARD, Intrinsic Therapeutics, Woburn, MA USA) inserted after the evacuation of the disc tissue during the limited discectomy.
Follow-up	**24 months**
Conflict of interest/source of funding	Patient follow-up and data analysis was financially supported by Intrinsic Therapeutics, Inc. None of the authors had a financial interest in any of the products or companies discussed.

Analysis

Follow-up issues:

- 88.9% (40/45) patients were eligible for follow-up at 12 months.
- 37.8% (17/45) patients were eligible for follow-up at 24 months.
- 66.7% (30/45) patients were eligible for radiographic data analysis at 12 months.
- 80% (36/45) patients had MRIs available for asymptomatic reherniation analysis at 12 months.

Study design issues:

- Multicentre study.

Study population issues:

- 1 patient had a concomitant musculoskeletal condition (arthritis) and 1 patient had a previous back procedure.
- 1 patient was included in the study despite having a VAS-leg< 40 (35/100).

Key efficacy and safety findings

Efficacy

Number of patients analysed: **40**

VAS scores

Significant reduction in VAS at all post-operative time points compared with pre-operative (p<0.0001).

Time point	Mean VAS back pain scores*	Mean VAS leg pain scores*
Preoperative	58	81
Week 6	18	12
Month 3	20	12
Month 6	20	10
Month 12	25	18

* Scores were read from a graph.

ODI scores

Significant reduction in ODI scores at all post-operative time points compared to pre-operative (p<0.0001).

Time point	Mean ODI patient function scores*
Preoperative	59
Week 6	18
Month 3	18
Month 6	12
Month 12	18

* Scores were read from a graph.

Maintenance of disc height

Small significant decrease of the mean disc height to 92.8% of baseline at 12 months (p<0.01).

Disc angle, spondylolisthesis, rotation and translation

No significant differences found between mean preoperative and 12-month evaluations.

Heterotopic ossification, spontaneous fusion

None found.

Degree of facet joint arthropathy

Grade (using Pathria classification)	% patients preoperatively	% patients at 12 months
0 (normal)	51.3% (20/39)	44.7% (17/38)
1 (mild – joint space narrowing)	38.5% (15/39)	42.1% (16/38)
2 (moderate – joint space narrowing + sclerosis/hypertrophy)	5.1% (2/39)	10.5% (4/38)
3 (severe – joint space narrowing with sclerosis/ hypertrophy and osteophytes)	5.1% (2/39)	2.6% (1/38)

Differences not significant (p=0.781).

Safety

- The patient with symptomatic reherniation required reoperation. The reason was that the device was implanted 3 mm too deep into the disc space.
- 2 other reoperations were performed: 1 for a contralateral herniation 3 weeks after surgery and 1 for excessive scar tissue, 5 months after the index surgery.
- Authors state that the contralateral herniation could have been caused by the implant (resulting in a pressure increase in the disc that could contribute to the rupture of the annulus at the contralateral side).
- Authors state that no device-related adverse events occurred in the study population.
- At 24 months follow-up, no patients had evidence of recurrent disc herniation or device migration, subsidence, or fracture/disassembly.
- No dural tears were reported.

Degree of disc degeneration

Grade (using Pfirrmann classification)	% patients preoperatively	% patients at 12 months
I (Bright white disc, homogeneous structure)	2.4% (1/42)	0
II (White disc, inhomogenous structure)	2.4% (1/42)	2.8% (1/36)
III (Grey disc, inhomogenous structure)	64.3% (27/42)	58.3% (21/36)
IV (Grey to black disc, inhomogenous structure)	30.9% (13/42)	38.9% (14/36)
V (Black disc, inhomogenous structure)	0	0

Differences not significant (p=0.857).

Reherniation rate

- Overall symptomatic reherniation rate: 2.4% (1/41)
- Asymptomatic reherniation rate (after MRI review): 2.8% (1/36) at 12 months.

Abbreviations used: DEXA, dual-energy X-ray absorptiometry; MRI, magnetic resonance imaging; ODI, Oswestry Disability Index; VAS, Visual Analogue Scale.

Efficacy

Reherniation rate

A non-randomised comparative study of 102 patients (30 patients treated by discectomy plus annular disc implant and 72 patients treated by discectomy only) reported no reherniations in the implant group within 2 years after surgery and 5 reherniations in the discectomy-only group: 3% (2/72) within 3 months and 4% (3/72) between 4 months and 2 years after surgery (level of significance not stated)[2].

A non-randomised comparative cohort study of 76 patients (30 patients from the same implant cohort as in the previous study and 46 patients treated by discectomy only) reported no reherniations 2 years after surgery in the implant group and 7% (3/46) in the discectomy-only group (no significant difference)[3].

A case series of 75 patients treated by discectomy plus annular disc implant within 2 different patient cohorts (with likely patient overlap with 2 other studies) reported an overall symptomatic reherniation rate of 1% (1/73) and asymptomatic reherniation rates (after MRI review) of 2% (1/66) at 12 months and 5% (2/39) at 24 months[4].

A case series of 45 patients treated by discectomy plus annular disc implant reported an overall symptomatic reherniation rate of 2% (1/41) 24 months after surgery and an asymptomatic reherniation rate of 3% (1/36) 12 months after surgery[5].

Disability

The non-randomised comparative study of 102 patients reported improvement in Oswestry Disability Index (ODI) scores in both groups. In the implant group, the ODI score decreased from 62.7 before surgery to 31.4 after 6 weeks and to 11.6 after 24 months. In the discectomy-only group, the ODI score decreased from 49.4 before surgery to 30.7 after 6 weeks and 19.8 after 24 months. The scores

were significantly different between the 2 groups at baseline (before surgery) (p=0.0004) but not at 6 weeks and 24 months[2].

The non-randomised comparative cohort study of 76 patients reported a significant improvement (p<0.01) in both cohorts at 6 weeks, 3, 6, 12 and 24 months with a greater mean 12-month improvement from baseline in the implant group of 47 compared with 35 in the discectomy-only group (p<0.005). Mean ODI scores after surgery were significantly better in the implant group compared with the discectomy-only group: 16 versus 22 after 12-month follow-up and 11 versus 21 after 24-month follow-up (p<0.05), despite an implant cohort presenting with worse ODI scores preoperatively[3].

The case series of 45 patients reported significant improvement in mean ODI scores at all postoperative time points (6 weeks, 3, 6 and 12 months) compared with preoperative ODI scores (p<0.0001)[5].

Pain

The non-randomised comparative study of 102 patients reported that back pain scores and leg pain scores (both measured on 100-point visual analogue scales, with higher scores indicating more severe pain) improved in both groups. Back pain scores improved from 66.3 before surgery to 10.5 after 24 months in the implant group and from 43.1 to 19.1 in the discectomy-only group (level of significance not stated). Leg pain scores improved from 79.8 before surgery to 8.9 after 24 months in the implant group and from 58.8 to 21.2 in the discectomy-only group (level of significance not stated). The scores for back and leg pain were significantly different between the 2 groups at baseline (before surgery; p≤0.0001). The scores for leg pain (but not for back pain) were significantly different between the 2 groups at 12 months and at 24 months (p<0.05)[2].

The non-randomised comparative cohort study of 76 patients reported significant back pain improvement (p<0.01) and leg pain improvement in both cohorts at 6 weeks, 3, 6, 12 and 24 months. Improvements in mean 12-month pain scores

from baseline between the implant group and the control group were significantly different (53 versus 31 for the back pain scores and 75 versus 53 for the leg pain scores, p<0.001). Mean pain scores were significantly lower in the implant group 12 months and 24 months after surgery: 13 versus 22 and 10 versus 21 (p<0.05) respectively for back pain and 5 versus 16 (p<0.01) and 9 versus 18 (p<0.05) respectively for leg pain[3].

The case series of 45 patients reported a significant reduction in mean Visual Analogue Scale (VAS) pain scores for both back and leg at all postoperative time points when compared with preoperative (p<0.0001)[5].

Disc height

The non-randomised comparative cohort study of 76 patients reported a mean loss of disc height from 8.60 mm to 7.63 mm (0.97 mm loss) in the implant group compared with 8.30 mm to 6.90 mm (1.40 mm loss) in the discectomy-only group 12 months after surgery (p=0.054).

The case series of 45 patients reported a decrease of the mean disc height to 93% of baseline after 12 months (p<0.01)[3].

Facet degeneration

A non-randomised comparative study of 157 patients treated by discectomy plus annular disc implant or discectomy only reported that the implant group had a significantly lower grade of facet degeneration (when grouping grades 0 and 1) 12 months after surgery (p=0.015) although there were no differences between both groups preoperatively. Twenty-four per cent (15/62) of the patients in the implant group exhibited facet degeneration when both groups were restricted to the same ODI and defect size requirements compared with 51% (18/35) in the discectomy-only group (p=0.008). Nineteen per cent (12/62) of patients in the implant group versus 31% (11/35) of patients in the discectomy-only group progressed to mild degeneration (Grade I) and 5% (3/62) versus 20% (7/35) respectively progressed to moderate degeneration (Grade II) after adjustment for

ODI and defect size requirements. The implant group exhibited a significantly greater range of motion 12 months after surgery (p=0.0092)[1].

The case series of 45 patients reported no significant differences in the degree of facet joint arthropathy or in the degree of disc degeneration before and after implantation[5].

Safety

Durotomy

Incidental durotomy (potentially causing cerebrospinal fluid leakage and complications such as headache) occurring during disc fragment removal was reported in 1 patient treated by discectomy plus annular disc implantation and in 1 patient treated by discectomy only in a non-randomised comparative study of 102 patients (30 patients treated by discectomy plus annular disc implant and 72 patients treated by discectomy only; level of significance not stated)[2]. Incidental durotomy was reported in 1 patient treated by discectomy plus annular disc implantation and in 1 patient treated by discectomy only in a non-randomised comparative cohort study of 76 patients (30 patients from the same implant cohort as in the previous study and 46 patients treated by discectomy only; level of significance not stated)[3].

Discitis

Suspected discitis 56 days after surgery was reported in 1 patient treated by discectomy plus annular disc implantation and in none of the patients treated by discectomy only in the non-randomised comparative cohort study of 76 patients (level of significance not stated). The infection was successfully treated by intravenous antibiotics[3].

Reoperation rate

Reoperations were reported in 3 patients treated by annular disc implantation after discectomy in a case series of 45 patients: 1 was a symptomatic reherniation 4 months after surgery because the device was implanted too deep into the disc space, 1 was a contralateral herniation 3 weeks after surgery

possibly caused by the implant, and 1 was for excessive scar tissue 5 months after surgery[5].

Validity and generalisability of the studies

- Most of the studies were funded by the manufacturer.
- There were suspected overlaps in the populations of patients between the implant population studied (63 patients) in the Trummer paper and the patient population from the Bouma paper but reporting different outcomes[1, 4]. Overlaps were also suspected between the implant group (30 patients) of the Vukas paper, the treatment cohort from the Parker paper, and the cohort A from the Bouma paper reporting the same efficacy and safety outcomes but compared with a different population[2, 3, 4].
- The follow-up never exceeded 24 months.
- There were no randomised control trials.
- The studies were all multicenter.
- Two case series included 2 patients who should have been excluded according to the patient selection criteria[4, 5]. One comparative study included 1 patient who was implanted in 2 levels[1].
- Mean preoperative ODI was usually different between the implant and the control groups.
- One comparative study reported that the only radiologist who interpreted the CT scans was not blinded to the treatment and control groups at follow-up[1].
- The number of reported safety outcomes was very limited.

Existing assessments of this procedure

A health technology assessment from a member of the International Network of Agencies for Health Technology Assessment (INAHTA) was published in German in 2013[6]. It states:

‘Conclusion and recommendation

Inclusion of the annular closure device Barricaid into the hospital benefit catalogue is not recommended. The currently available evidence is not sufficient to evaluate efficacy and safety of the implantation of Barricaid in comparison to standard discectomy. We recommend re-evaluation from 2017 onwards, after results from currently ongoing clinical studies have been published.'

Related NICE guidance

Below is a list of NICE guidance related to this procedure. Appendix B gives details of the recommendations made in each piece of guidance listed.

Interventional procedures

- Non rigid stabilisation techniques for the treatment of low back pain. NICE interventional procedure guidance 366 (2010). Available from http://www.nice.org.uk/guidance/IPG366
- Percutaneous intradiscal laser ablation in the lumbar spine. NICE interventional procedure guidance 357 (2010). Available from http://www.nice.org.uk/guidance/IPG357
- Lateral (including extreme, extra and direct lateral) interbody fusion in the lumbar spine. NICE interventional procedure guidance 321 (2009). Available from http://www.nice.org.uk/guidance/IPG321
- Percutaneous intradiscal electrothermal therapy for low back pain. NICE interventional procedure guidance 319 (2009). Available from http://www.nice.org.uk/guidance/IPG319
- Prosthetic intervertebral disc replacement in the lumbar spine. NICE interventional procedure guidance 306 (2009). Available from http://www.nice.org.uk/guidance/IPG306
- Percutaneous endoscopic laser lumbar discectomy. NICE interventional procedure guidance 300 (2009). Available from http://www.nice.org.uk/guidance/IPG300
- Percutaneous disc decompression using coblation for lower back pain. NICE interventional procedure guidance 173 (2006). Available from http://www.nice.org.uk/guidance/IPG173

- Automated percutaneous mechanical lumbar discectomy. NICE interventional procedure guidance 141 (2005). Available from http://www.nice.org.uk/guidance/IPG141
- Percutaneous intradiscal radiofrequency thermocoagulation for lower back pain. NICE interventional procedure guidance 83 (2004). Available from http://www.nice.org.uk/guidance/IPG83

Clinical guidelines

- Low back pain: early management of persistent non-specific low back pain. NICE clinical guideline 88 (2009). Available from http://www.nice.org.uk/guidance/CG88

Specialist advisers' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their specialist society or royal college. The advice received is their individual opinion and does not represent the view of the society.

Mr A Casey, Mr M McCarthy and Mr Kia Rezajooi (British Association of Spinal Surgeons).

- None of the specialist advisers have performed the procedure.
- One adviser considered the procedure to be definitely novel and of uncertain safety and efficacy, 1 adviser considered the procedure to be definitely novel and of uncertain safety and efficacy (the first in a new class of procedure) and 1 adviser considered the procedure to be a minor variation of an existing procedure, which is unlikely to alter that procedure's safety and efficacy.
- Comparators for this procedure would be lumbar discectomy with no implant and lumbar discectomy and fusion.
- Theoretical adverse events include haematoma, cauda equina damage, implant displacement causing nerve root damage, pain, numbness, weakness and neurological compression.

- No anecdotal adverse events were listed.
- No adverse events reported in the literature were listed.
- Key efficacy outcome: recurrence of herniation in the long term.
- There is uncertainty about the long-term efficacy of the procedure.
- One adviser commented that 'if this procedure is proven to be a safe and efficacious method of reducing the incidence of symptomatic recurrent disc herniation, its use may be indicated in almost all primary disc herniations. However, as we currently do not have an effective method of predicting the risk factors for symptomatic recurrent disc herniation, there is a potential risk of overtreatment and overuse of this procedure'. He added that 'should this procedure significantly reduce the incidence of recurrent disc herniation, there would be a potential cost saving by reducing the need for revision surgery and further treatment for recurrent disc herniations. There could also be a potentially significant improvement in patient outcomes after primary lumbar discectomy'.
- Two advisers thought that the procedure would have a minor impact on the NHS, in terms of numbers of patients eligible for treatment and use of resources, and 1 adviser thought the impact would be moderate.

Patient commentators' opinions

NICE's Public Involvement Programme sent 0 questionnaires to NHS trusts for distribution to patients who had the procedure (or their carers).

NICE's Public Involvement Programme was unable to gather patient commentary for this procedure.

Issues for consideration by IPAC

- Future/ongoing studies:

- NCT01283438: ‘A Prospective, Randomized, Multicenter Study to Demonstrate the Superiority of the Barricaid to Discectomy for Primary Lumbar Disc Herniation.’ Randomised comparative study in 5 different European countries; estimated enrolment: 500 patients; estimated completion date: January 2016. (Manufacturer study).
- NCT01534065: ‘A Multicenter, Post Marketing Surveillance Study to Monitor the Safety and Performance of the Barricaid® ARD in the Treatment of Back and Radicular Pain Caused by Primary Lumbar Disc Herniation.’ Case series; enrolment: 45. Final data collection: March 2013. (Manufacturer study).

References

1. Trummer M, Eustacchio S, Barth M et al (2013) Protecting facet joints post-lumbar discectomy: Barricaid annular closure device reduces risk of facet degeneration. Clinical Neurology & Neurosurgery 115 (8) 1440-1445.
2. Vukas D, Ledic D, Grahovac G et al (2013) Clinical outcomes in patients after lumbar disk surgery with annular reinforcement device: two-year follow up. Acta Clinica Croatica 52 (1) 87-91.
3. Parker SL, Grahovac G, Vukas D et al [In press] Effect of An Annular Closure Device (Barricaid) on Same Level Recurrent Disc Herniation and Disc Height Loss After Primary Lumbar Discectomy: Two-Year Results of a Multi-Center Prospective Cohort Study. J.Spinal Disord.Tech.
4. Bouma GJ, Barth M, Ledic D et al (2013) The high-risk discectomy patient: prevention of reherniation in patients with large anular defects using an anular closure device. European Spine Journal 22 (5) 1030-1036.
5. Lequin M, Barth M, Thomé C et al (2012) Primary Limited Lumbar Discectomy with an Annulus Closure Device: One-Year Clinical and Radiographic Results from a Prospective, Multi-Center Study. Korean J Spine 9(4):340-347.
6. Zechmeister-Koss I, Nachtnebel A (2013) Implantation einer lumbalen Bandscheinbenring-Teilendoprothese (Barricaid). [Implantation of a lumbar artificial endoprosthesis (anuloplasty/anular repair device)] Vienna: Ludwig Boltzmann Institut fuer Health Technology Assessment (LBIHTA). Decision Support Document 65.

Appendix A: Additional papers on insertion of an annular disc implant at lumbar discectomy

There were no additional papers identified.

Appendix B: Related NICE guidance for insertion of an annular disc implant at lumbar discectomy

Guidance	Recommendations
Interventional procedures	**Non rigid stabilisation techniques for the treatment of low back pain. NICE interventional procedure guidance 366 (2010)** 1.1 Current evidence on the efficacy of non-rigid stabilisation techniques for the treatment of low back pain shows that these procedures are efficacious for a proportion of patients with intractable back pain. There are no major safety concerns. Therefore these procedures may be used provided that normal arrangements are in place for clinical governance, consent and audit. 1.2 Patient selection should be carried out by specialist spinal surgeons who are able to offer patients a range of surgical treatment options. **Percutaneous intradiscal laser ablation in the lumbar spine. NICE interventional procedure guidance 357 (2010)** 1.1 Current evidence on the safety and efficacy of percutaneous intradiscal laser ablation in the lumbar spine is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit. 1.2 Patients selected for the procedure should be limited to those with severe pain refractory to conservative treatment, in whom imaging studies show bulging of an intact disc, and who do not have neurological deficit requiring surgical decompression. **Lateral (including extreme, extra and direct lateral) interbody fusion in the lumbar spine. NICE interventional procedure guidance 321 (2009)** 1.1 Current evidence on the safety and efficacy of lateral (including extreme, extra and direct lateral) interbody fusion in the lumbar spine is inadequate in quantity and quality. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research. 1.2 Clinicians wishing to undertake lateral interbody fusion in the lumbar spine should take the following actions. • Inform the clinical governance leads in their Trusts. • Ensure that patients and their carers understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. In addition, the use of NICE's information for patients ('Understanding NICE guidance') is recommended.

	• Audit and review clinical outcomes of all patients having lateral interbody fusion in the lumbar spine (see section 3.1). 1.3 This procedure should only be carried out by surgeons with specific training in the technique, who should perform their initial procedures with an experienced mentor. 1.4 NICE encourages further research into lateral interbody fusion in the lumbar spine. Research outcomes should include fusion rates, pain and functional scores, quality of life measures and the frequency of both early and late complications. NICE may review the procedure on publication of further evidence. **Percutaneous intradiscal electrothermal therapy for low back pain. NICE interventional procedure guidance 319 (2009)** 1.1 Current evidence on the safety and efficacy of percutaneous intradiscal electrothermal therapy for low back pain is inconsistent. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research. 1.2 Clinicians wishing to undertake percutaneous intradiscal electrothermal therapy for low back pain should take the following actions. • Inform the clinical governance leads in their Trusts. • Ensure that patients and their carers understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. In addition, the use of NICE's information for patients ('Understanding NICE guidance') is recommended. • Audit and review clinical outcomes of all patients having percutaneous intradiscal electrothermal therapy for low back pain (see section 3.1). 1.3 NICE encourages further research into percutaneous intradiscal electrothermal therapy for low back pain. Research should describe patient selection, use validated measures of long-term pain relief and quality of life, address the role of the procedure in avoiding major surgery, and measure long-term safety outcomes. **Prosthetic intervertebral disc replacement in the lumbar spine. NICE interventional procedure guidance 306 (2009).** 1.1 Current evidence on the safety and efficacy of prosthetic intervertebral disc replacement in the lumbar spine is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit. 1.2 A multidisciplinary team with specialist expertise in the treatment of degenerative spine disease should be involved in patient selection for prosthetic intervertebral disc replacement

	in the lumbar spine. The procedure should only be carried out in patients for whom conservative treatment options have failed or are contraindicated. 1.3 The current evidence includes studies with a maximum follow-up of 13 years, but the majority of evidence is from studies with shorter durations of follow-up. NICE encourages clinicians to continue to collect and publish data on longer-term outcomes, which should include information about patient selection and the need for further surgery. **Percutaneous endoscopic laser lumbar discectomy. NICE interventional procedure guidance 300 (2009)** 1.1 Current evidence on the safety and efficacy of percutaneous endoscopic laser lumbar discectomy is inadequate in quantity and quality. Therefore this procedure should only be used with special arrangements for clinical governance, consent, and audit or research. 1.2 Clinicians wishing to undertake percutaneous endoscopic laser lumbar discectomy should take the following actions. • Inform the clinical governance leads in their Trusts. • Ensure that patients and their carers understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. In addition, the use of NICE's information for patients ('Understanding NICE guidance') is recommended. • Audit and review clinical outcomes of all patients having percutaneous endoscopic laser lumbar discectomy (see section 3.1). 1.3 Surgeons undertaking this procedure should have specific training in the use of lasers and in endoscopy of the spinal canal. 1.4 NICE encourages further research into percutaneous endoscopic laser lumbar discectomy and may review the procedure on publication of further evidence. Research studies should provide long-term outcome data. **Percutaneous disc decompression using coblation for lower back pain. NICE interventional procedure guidance 173 (2006)** 1.1 Current evidence suggests that there are no major safety concerns associated with the use of percutaneous disc decompression using coblation for lower back pain. There is some evidence of short-term efficacy; however, this is not sufficient to support the use of this procedure without special arrangements for consent and for audit or research. 1.2 Clinicians wishing to undertake percutaneous disc decompression using coblation for lower back pain should take the following actions. • Inform the clinical governance leads in their Trusts. • Ensure that patients understand the uncertainty about the

	procedure's efficacy and provide them with clear written information. Use of the Institute's information for the public is recommended. • Audit and review clinical outcomes of all patients having percutaneous disc decompression using coblation for lower back pain. 1.3 Further research will be useful in reducing the current uncertainty, and clinicians are encouraged to collect long-term follow-up data. The Institute may review the procedure upon publication of further evidence. **Automated percutaneous mechanical lumbar discectomy. NICE interventional procedure guidance 141 (2005)** 1.1 Current evidence suggests that there are no major safety concerns associated with automated percutaneous mechanical lumbar discectomy. There is limited evidence of efficacy based on uncontrolled case series of heterogeneous groups of patients, but evidence from small randomised controlled trials shows conflicting results. In view of the uncertainties about the efficacy of the procedure, it should not be used without special arrangements for consent and for audit or research. 1.2 Clinicians wishing to undertake automated percutaneous mechanical lumbar discectomy should take the following actions. • Inform the clinical governance leads in their Trusts. • Ensure that patients understand the uncertainty about the procedure's efficacy and provide them with clear written information. In addition, use of the Institute's information for the public is recommended. • Audit and review clinical outcomes of all patients having automated mechanical percutaneous lumbar discectomy. The Institute may review the procedure upon publication of further evidence. **Percutaneous intradiscal radiofrequency thermocoagulation for lower back pain. NICE interventional procedure guidance 83 (2004)** 1.1 Current evidence on the safety and efficacy of percutaneous intradiscal radiofrequency thermocoagulation for lower back pain does not appear adequate to support the use of this procedure without special arrangements for consent and for audit or research. 1.2 Clinicians wishing to undertake percutaneous intradiscal radiofrequency thermocoagulation for lower back pain should take the following actions. • Inform the clinical governance leads in their Trusts. • Ensure that patients understand the uncertainty about the procedure's efficacy and provide them with clear written information. Use of the Institute's information for the public is recommended. • Audit and review clinical outcomes of all patients having

	percutaneous intradiscal radiofrequency thermocoagulation for lower back pain. 1.3 Further research will be useful in reducing the current uncertainty and clinicians are encouraged to collect longer-term follow-up data. The Institute may review the procedure upon publication of further evidence.
Clinical guidelines	**Low back pain: early management of persistent non-specific low back pain. NICE clinical guideline 88 (2009)** This guideline covers the early treatment and management of persistent or recurrent low back pain, defined as non-specific low back pain that has lasted for more than 6 weeks, but for less than 12 months. It does not address the management of severe disabling low back pain that has lasted over 12 months. **1.1 Assessment and imaging** 1.1.1 Keep diagnosis under review. 1.1.2 Do not offer X-ray of the lumbar spine for the management of non-specific low back pain. 1.1.3 Consider MRI (magnetic resonance imaging) when a diagnosis of spinal malignancy, infection, fracture, cauda equina syndrome or ankylosing spondylitis or another inflammatory disorder is suspected. 1.1.4 Only offer an MRI scan for non-specific low back pain within the context of a referral for an opinion on spinal fusion (see section 1.9). **1.2 Information, education and patient preferences** 1.2.1 Provide people with advice and information to promote self-management of their low back pain. 1.2.2 Offer educational advice that: • includes information on the nature of non-specific low back pain • encourages the person to be physically active and continue with normal activities as far as possible. 1.2.3 Include an educational component consistent with this guideline as part of other interventions, but do not offer stand-alone formal education programmes. 1.2.4 Take into account the person's expectations and preferences when considering recommended treatments, but do not use their expectations and preferences to predict their response to treatments. 1.2.5 Offer one of the following treatment options, taking into account patient preference: an exercise programme (see section 1.3.3), a course of manual therapy (see section 1.4.1) or a course of acupuncture (see section 1.6.1). Consider offering another of these options if the chosen treatment does not result in satisfactory improvement. **1.3 Physical activity and exercise** 1.3.1 Advise people with low back pain that staying physically

	active is likely to be beneficial. 1.3.2 Advise people with low back pain to exercise. 1.3.3 Consider offering a structured exercise programme tailored to the person: • This should comprise up to a maximum of eight sessions over a period of up to 12 weeks. • Offer a group supervised exercise programme, in a group of up to 10 people. • A one-to-one supervised exercise programme may be offered if a group programme is not suitable for a particular person. 1.3.4 Exercise programmes may include the following elements: • aerobic activity • movement instruction • muscle strengthening • postural control • stretching. **1.4 Manual therapy** The manual therapies reviewed were spinal manipulation (a low-amplitude, high-velocity movement at the limit of joint range that takes the joint beyond the passive range of movement), spinal mobilisation (joint movement within the normal range of motion) and massage (manual manipulation or mobilisation of soft tissues). Collectively these are all manual therapy. Mobilisation and massage are performed by a wide variety of practitioners. Manipulation can be performed by chiropractors and osteopaths, as well as by doctors and physiotherapists who have undergone specialist postgraduate training in manipulation. 1.4.1 Consider offering a course of manual therapy, including spinal manipulation, comprising up to a maximum of nine sessions over a period of up to 12 weeks. **1.5 Other non-pharmacological therapies** **Electrotherapy modalities** 1.5.1 Do not offer laser therapy. 1.5.2 Do not offer interferential therapy. 1.5.3 Do not offer therapeutic ultrasound. **Transcutaneous nerve stimulation** 1.5.4 Do not offer transcutaneous electrical nerve simulation (TENS). **Lumbar supports** 1.5.5 Do not offer lumbar supports. **Traction** 1.5.6 Do not offer traction. **1.6 Invasive procedures**

	1.6.1 Consider offering a course of acupuncture needling comprising up to a maximum of 10 sessions over a period of up to 12 weeks. 1.6.2 Do not offer injections of therapeutic substances into the back for non-specific low back pain. **1.7 Combined physical and psychological treatment programme** 1.7.1 Consider referral for a combined physical and psychological treatment programme, comprising around 100 hours over a maximum of 8 weeks, for people who: • have received at least one less intensive treatment (see section 1.2.5) and • have high disability and/or significant psychological distress. 1.7.2 Combined physical and psychological treatment programmes should include a cognitive behavioural approach and exercise. 1**.8 Pharmacological therapies** Both weak opioids and strong opioids are discussed in the recommendations in this section. Examples of weak opioids are codeine and dihydrocodeine (these are sometimes combined with paracetamol as co-codamol or co-dydramol, respectively). Examples of strong opioids are buprenorphine, diamorphine, fentanyl and oxycodone. Some opioids, such as tramadol, are difficult to classify because they can act like a weak or strong opioid depending on the dose used and the circumstances. No opioids, cyclooxygenase 2 (COX-2) inhibitors or tricyclic antidepressants and only some non-steroidal anti-inflammatory drugs (NSAIDs) have a UK marketing authorisation for treating low back pain. If a drug without a marketing authorisation for this indication is prescribed, informed consent should be obtained and documented. 1.8.1 Advise the person to take regular paracetamol as the first medication option. 1.8.2 When paracetamol alone provides insufficient pain relief, offer: • non-steroidal anti-inflammatory drugs (NSAIDs) and/or weak opioids • Take into account the individual risk of side effects and patient preference. 1.8.3 Give due consideration to the risk of side effects from NSAIDs, especially in: • older people • other people at increased risk of experiencing side effects. 1.8.4 When offering treatment with an oral NSAID/COX-2 (cyclooxygenase 2) inhibitor, the first choice should be either a standard NSAID or a COX-2 inhibitor. In either case, for

	people over 45 these should be co-prescribed with a PPI (proton pump inhibitor), choosing the one with the lowest acquisition cost. [This recommendation is adapted from 'Osteoarthritis: the care and management of osteoarthritis in adults' (NICE clinical guideline 59).] 1.8.5 Consider offering tricyclic antidepressants if other medications provide insufficient pain relief. Start at a low dosage and increase up to the maximum antidepressant dosage until therapeutic effect is achieved or unacceptable side effects prevent further increase. 1.8.6 Consider offering strong opioids for short-term use to people in severe pain. 1.8.7 Consider referral for specialist assessment for people who may require prolonged use of strong opioids. 1.8.8 Give due consideration to the risk of opioid dependence and side effects for both strong and weak opioids. 1.8.9 Base decisions on continuation of medications on individual response. 1.8.10 Do not offer selective serotonin reuptake inhibitors (SSRIs) for treating pain. **1.9 Referral for surgery** 1.9.1 Consider referral for an opinion on spinal fusion for people who: • have completed an optimal package of care, including a combined physical and psychological treatment programme (see section 1.7) and • still have severe non-specific low back pain for which they would consider surgery. 1.9.2 Offer anyone with psychological distress appropriate treatment for this before referral for an opinion on spinal fusion. 1.9.3 Refer the patient to a specialist spinal surgical service if spinal fusion is being considered. Give due consideration to the possible risks for that patient. 1.9.4 Do not refer people for any of the following procedures: • intradiscal electrothermal therapy (IDET) • percutaneous intradiscal radiofrequency thermocoagulation (PIRFT) • radiofrequency facet joint denervation.

Appendix C: Literature search for insertion of an annular disc implant at lumbar discectomy

Databases	Date searched	Version/files	No. retrieved
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	16/07/2014	Issue 7 of 12, July 2014	9
Database of Abstracts of Reviews of Effects – DARE (Cochrane Library)	16/07/2014	Issue 2 of 4, April 2014	3
HTA database (Cochrane Library)	16/04/2014	Issue 2 of 4, April 2014	5
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	16/04/2014	Issue 6 of 12, June 2014	44
MEDLINE (Ovid)	16/07/2014	1946 to July Week 1 2014	5
MEDLINE In-Process (Ovid)	16/07/2014	July 15, 2014	9
EMBASE (Ovid)	16/07/2014	1974 to 2014 July 15 (Week 28)	8
CINAHL (NLH Search 2.0)	n/a		
PubMed	16/07/2014		23
JournalTOCS	n/a		

Trial sources searched on 18/02/2014

- National Institute for Health Research Clinical Research Network Coordinating Centre (NIHR CRN CC) Portfolio Database
- Current Controlled Trials *meta*Register of Controlled Trials – *m*RCT
- Clinicaltrials.gov

Websites searched on 17/02/2014-18/02/2014

- National Institute for Health and Care Excellence (NICE)
- NHS England
- Food and Drug Administration (FDA) - MAUDE database
- French Health Authority (FHA)
- Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP – S)
- Australia and New Zealand Horizon Scanning Network (ANZHSN)
- Conference websites
- General internet search

The following search strategy was used to identify papers in MEDLINE. A similar strategy was used to identify papers in other databases.

1 Diskectomy/
2 (diskectom* or discectom*).tw.
3 (microdisk* or microdisc*).tw.
4 or/1-3
5 ((annul* or anul*) adj3 (reconstruct* or replace* or rebuild* or rehabilit* or repair* or restor* or reset*)).tw.
6 annuloplasty.tw.
7 "Prostheses and Implants"/
8 (prosthe* or endoprosthe* or implant*).tw.
9 Barricaid.tw.
10 or/5-9
11 Sciatica/
12 sciatica.tw.
13 ((low* adj3 back) and (pain* or ache* or discomfort* or distress* or irritat* or sore* or strain* or tender*)).tw.
14 Low Back Pain/
15 (lumbar adj3 (degenerat* or deteriorat* or decay* or worse*) adj3 (disc* or disk*)).tw.
16 Intervertebral Disk Displacement/
17 Intervertebral Disk Degeneration/
18 ((hernia* or prolaps* or slip* or extrud* or ruptur* or collaps* or burst* or bulg* or sequester* or transligament*) adj3 (disc* or disk* or "nucleus pulposus")).tw.
19 or/11-18
20 4 and 10 and 19
21 animals/ not humans/
22 20 not 21